

AUG 30 2007

PATENT

Application No.: 10/627,591  
Attorney Docket No. 0029.10In the claims:

1-22. (Cancelled)

23. (Previously presented) A device for increasing the bioavailability of an aerosolized active agent, said device comprising a flow restrictor for limiting the flow of an aerosolized active agent formulation to a human patient to less than 17 liters per minute, wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant.

24. (Previously presented) The device of claim 23 wherein the flow restrictor comprises an orifice.

25. (Withdrawn) The device of claim 24 wherein the flow restrictor comprises apertures of 0.5 to 0.9 mm in diameter.

26. (Previously presented) The device of claim 23 wherein the flow restrictor is a valve that provides for decreasing resistance with increasing flow rate.

27. (Withdrawn) The device of claim 23 wherein the flow restrictor is a valve that provides for high resistance at all flow rates except a desired flow rate range.

28. (Previously presented) The device of claim 23 wherein the device is adapted to be used with an active agent selected from the group consisting of insulin, cyclosporin, parathyroid hormone, follicle stimulating hormone, alpha-1-antitrypsin, budesonide, human growth hormone, growth hormone releasing hormone, interferon alpha, interferon beta, growth colony stimulating factor, luteinizing hormone releasing hormone, calcitonin, low molecular weight heparin, somatostatin, respiratory syncytial virus antibody, erythropoietin, Factor VIII, Factor IX, ceredase, cerezyme and analogues, agonists and antagonists thereof.

29. (Previously presented) The device of claim 23 wherein the active agent formulation is a powder and wherein the device is adapted to aerosolize the active agent formulation.

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30. (Previously presented) The device of claim 23 wherein the active agent formulation is contained in a blister and wherein the device is adapted to receive the blister.

31. (Previously presented) The device of claim 23 wherein the device is adapted to aerosolize a powder active agent formulation.

32. (Previously presented) The device of claim 31 wherein the device is adapted to aerosolize the powder active agent formulation using compressed air.

33. (Previously presented) A device for delivering an aerosolized active agent to the lungs of a human patient, wherein said device is adapted to deliver an aerosolized active agent formulation at an inspiratory flow rate of less than 17 liters per minute, wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant.

34. (Previously presented) The device of claim 33 wherein the device is adapted to be used with an aerosolized active agent formulation in dry powder form.

35. (Previously presented) The device of claim 33 wherein the device is adapted to deliver the aerosolized active agent formulation at an inspiratory flow rate of 10 liters per minute or less.

36. (Previously presented) The device of claim 33 wherein the active agent formulation is a powder and wherein the device is adapted to aerosolize the active agent formulation.

37. (Previously presented) The device of claim 33 wherein the active agent formulation is contained in a blister and wherein the device is adapted to receive the blister.

38. (Previously presented) A device for delivering aerosolized insulin to the lungs of a human patient, wherein said device comprises a flow restrictor to restrict an inspiratory

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flow rate of an aerosolized insulin formulation to less than 17 liters per minute and wherein the device is adapted to aerosolize the insulin.

39. (Previously presented) The device of claim 38 wherein the inspiratory flow rate is 10 liters per minute or less.

40. (Previously presented) The device of claim 38 wherein the active agent formulation is a powder and wherein the device is adapted to aerosolize the active agent formulation.

41. (Previously presented) The device of claim 38 wherein the active agent formulation is contained in a blister and wherein the device is adapted to receive the blister.

42. (Previously presented) A device for delivering an aerosolized active agent to the lungs of a human patient, wherein said device comprises one or more orifices sized so that an aerosolized active agent formulation may be delivered at an inspiratory flow rate of less than 17 liters per minute, wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant.

43. (Previously presented) The device of claim 42 wherein the device is adapted to deliver an aerosolized insulin formulation to the lungs.

44. (Previously presented) The device of claim 42 wherein the orifices are sized so that the aerosolized active agent formulation may be delivered at an inspiratory flow rate of 10 liters per minute or less.

45. (Previously presented) The device of claim 42 wherein the active agent formulation is a powder and wherein the device is adapted to aerosolize the active agent formulation.

46. (Previously presented) The device of claim 42 wherein the active agent formulation is contained in a blister and wherein the device is adapted to receive the blister.

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47. (Previously presented) A device for delivering an aerosolized active agent to the lungs of a human patient, said device comprising:

a chamber in flow communication with a mouthpiece;  
means for aerosolizing the active agent; and  
means for limiting an inspiratory flow rate through the mouthpiece to less than 17 liters per minute.

whereby an aerosolized active agent formulation in the chamber may be delivered to the human patient, the active agent formulation being (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant.

48. (Previously presented) The device of claim 47 wherein the inspiratory flow rate is limited to 10 liters per minute or less.

49. (Previously presented) The device of claim 47 wherein the device is adapted to deliver an aerosolized insulin formulation to the lungs.

50. (Previously presented) The device of claim 47 further comprising means for aerosolizing the active agent.

51. (Previously presented) The device of claim 47 wherein the active agent formulation is a powder and wherein the device is adapted to aerosolize the active agent formulation.

52. (Previously presented) The device of claim 47 wherein the active agent formulation is contained in a blister and wherein the device is adapted to receive the blister.